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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,230	01/24/2002	Jan E. Schnitzer	1440.1069-013	6912

21005 7590 03/25/2003

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/25/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/056,230

Applicant(s)
Schnitzer

Examiner
Unger

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 24, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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1. Claims 1-17 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claim 1 is drawn to a method of delivering an agent of interest to a luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to caveolae, classified in Class 424, subclass 130.1.

Group 2. Claim 1 is drawn to a method of delivering an agent of interest to a luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to G domains, classified in Class 424, subclass 130.1.

Group 3. Claim 1 is drawn to a method of delivering an agent of interest to a luminal surface of vascular endothelium in a tissue-specific

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manner wherein the agent binds to caveolae associated with G domains, classified in Class 424, subclass 130.1.

Group 4. Claim 2 is drawn to a method of delivering an agent of interest into a luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to caveolae, classified in Class 424, subclass 130.1.

Group 5. Claim 2 is drawn to a method of delivering an agent of interest into a luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to G domains, classified in Class 424, subclass 130.1.

Group 6. Claim 2 is drawn to a method of delivering an agent of interest into a luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to caveolae associated with G domains, classified in Class 424, subclass 130.1.

Group 7. Claim 2 is drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to caveolae, classified in Class 424, subclass 130.1.

Group 8. Claim 2 is drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to G domains, classified in Class 424, subclass 130.1.

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Group 9. Claim 2 is drawn to a method of delivering an agent of interest across luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to caveolae associated with G domains, classified in Class 424, subclass 130.1.

Group 10. Claim 2 is drawn to a method of delivering an agent of interest into and across a luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to caveolae, classified in Class 424, subclass 130.1.

Group 11. Claim 2 is drawn to a method of delivering an agent of interest into and across luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to G domains, classified in Class 424, subclass 130.1.

Group 12. Claim 2 is drawn to a method of delivering an agent of interest into and across luminal surface of vascular endothelium in a tissue-specific manner wherein the agent binds to caveolae associated with G domains, classified in Class 424, subclass 130.1.

3. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 3 drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae, wherein the agent of interest is a single component wherein the active component and the transport component are the same

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component classified in Class 424, subclass 130.1, Class 514, subclass 2+ and claims 4 and 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 13. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae, wherein the agent of interest is a single component wherein the agent is an antibody classified in Class 424, subclass 130.1.

Group 14. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae, wherein the agent of interest is a single component wherein the agent is a drug classified in Class 512, subclass 2+.

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Group 15. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae, wherein the agent of interest is a single component wherein the agent is a toxin classified in Class 514, subclass 2+.

Group 16. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae, wherein the agent of interest is a single component wherein the agent is a diagnostic agent classified in Class 424, subclass 130.1, Class 514, subclass 2+.

4. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 3 drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to G domains, wherein the agent of interest is a single component classified in Class 424, subclass 130.1 and claims 4 and 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking

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claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 17. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to G domains, wherein the agent of interest is a single component wherein the agent is an antibody classified in Class 424, subclass 130.1.

Group 18. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to G domains, wherein the agent of interest is a single component wherein the agent is a drug classified in Class 512, subclass 2+.

Group 19. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to G domains, wherein the agent of interest is a single component wherein the agent is a toxin classified in Class 514, subclass 2+.

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Group 20. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to G domains, wherein the agent of interest is a single component wherein the agent is a diagnostic agent classified in Class 424, subclass 130.1, Class 514, subclass 2+.

5. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 3 drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae associated with G domains, wherein the agent of interest is a single component classified in Class 424, subclass 130.1 and claims 4 and 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of

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35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 21. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae associated with G domains, wherein the agent of interest is a single component wherein the agent is an antibody classified in Class 424, subclass 130.1.

Group 22. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae associated with G domains, wherein the agent of interest is a single component wherein the agent is a drug classified in Class 512, subclass 2+.

Group 23. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae associated with G domains, wherein the agent of interest is a single component wherein the agent is a toxin classified in Class 514, subclass 2+.

Group 24. Claims 3-5, 10-11 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner

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wherein the agent binds to caveolae associated with G domains, wherein the agent of interest is a single component wherein the agent is a diagnostic agent classified in Class 424, subclass 130.1, Class 514, subclass 2+.

6. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 3 drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae, wherein the agent of interest comprises an active agent component and a transport agent component wherein the two components are not the same component classified in Class 424, subclass 130.1, Class 514, subclass 2+, Class 536, subclass 23.1, and claim 4. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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Groups 25-304 Claims 3-5, 8, 9, 12, 14 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae, wherein the agent of interest comprises an active agent component and a transport agent component wherein the two components are not the same component, wherein the active agent component is one of the five active agent components claimed in claim 8 and the transport component is one of the six components claimed in claim 12, wherein the tissue is one of the seven tissues claimed in claim 8. Each of the combinations, that is of active agent component, transport agent components and tissue types are a separate, distinct invention and that the number of combinations of groups claimed has been found to be 280. Applicant is required to elect a single invention for examination. Claims 6, 7, 13, 15-17 will be examined as they are drawn to the elected invention.

7. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 3 drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to G domains, wherein the agent of interest comprises an active agent component and a transport agent component wherein the two components are not the same component classified in Class 424, subclass 130.1,

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Class 514, subclass 2+, Class 536, subclass 23.1, and claim 4. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 305-584 Claims 3-5, 8, 9, 12, 14 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to G domains, wherein the agent of interest comprises an active agent component and a transport agent component wherein the two components are not the same component, wherein the active agent component is one of the five active agent components claimed in claim 8 and the transport agent component is one of the seven components claimed in claim 12, wherein the tissue is one of the seven tissues claimed in claim 8. Each of the combinations, that is of active agent component, transport agent components and tissue types are a separate,

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distinct invention and that the number of combinations of groups claimed has been found to be 280. Applicant is required to elect a single invention for examination. Claims 6, 7, 13, 15-17 will be examined as they are drawn to the elected invention.

8. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 3 drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae associated with G domains, wherein the agent of interest comprises an active agent component and a transport agent component wherein the two components are not the same component classified in Class 424, subclass 130.1, Class 514, subclass 2+, Class 536, subclass 23.1, and claim 4. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are

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no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 585-864 Claims 3-5, 8, 9, 12, 14 are drawn to a method of delivering an agent of interest across a luminal surface of vascular endothelium and from one side of an underlying cell to another side in a tissue-specific manner wherein the agent binds to caveolae associated with G domains, wherein the agent of interest comprises an active agent component and a transport agent component wherein the two components are not the same component, wherein the active agent component is one of the five active agent components claimed in claim 8 and the transport agent component is one of the seven components claimed in claim 12, wherein the tissue is one of the seven tissues claimed in claim 8. Each of the combinations, that is of active agent component, transport agent components and tissue types are a separate, distinct invention and that the number of combinations of groups claimed has been found to be 280. Applicant is required to elect a single invention for examination. Claims 6, 7, 13, 15-17 will be examined as they are drawn to the elected invention.

9. The inventions are distinct, each from the other because of the following reasons:

Inventions III-VII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

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10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

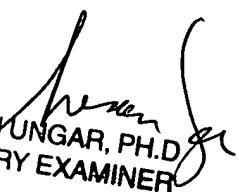
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

Serial No: 10/056,230

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Primary Patent Examiner
March 24, 2003